

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application No.: 10/643,674
Filing Date: August 19, 2003
Applicant: Suong-Hyu Hyon, et al.
Group Art Unit: 1796
Examiner: Susan W. Berman
Title: ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE MOLDED
ARTICLE FOR ARTIFICIAL JOINTS AND METHOD OF PREPARING
THE SAME
Attorney Docket: 1736-000001/REB

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REPLY BRIEF UNDER 37 CFR § 41.41

This Reply Brief is filed in response to the Examiner's Answer mailed December 29, 2009 (herein, the "Answer"), in the appeal from the Office Action mailed October 28, 2008 (herein the "Final Action") and the subsequent Advisory Action mailed May 26, 2009, for which a Notice of Appeal was filed on April 28, 2009.

Arguments

I. The claims do not recapture surrendered subject matter.

All claims have been rejected under 35 U.S.C. § 251 as allegedly being an improper recapture of subject matter surrendered in the application for the patent (U.S. Patent No. 6,168,626, Hyon et al., issued January 2, 2001, herein referred to as “the ‘626 Patent”) upon which the present reissue is based. As Applicants discussed in their Brief, the recapture rejection should be reversed for either or both of two reasons.

- First, the present reissue claims were prosecuted for a different invention than that prosecuted in the ‘626 Patent, embodying a broadening aspect never presented during prosecution of the ‘626 Patent such that any other broadening aspects do not relate to surrendered subject matter.
- Second, even if the present claims are viewed as having broadening aspects related to surrendered subject matter, they are materially narrowed in other aspects so as to avoid recapture.

Thus, rejection fails under either or both of the second and third prongs of the analysis outlined in *Pannu v. Storz Instruments, Inc.*, 258 F.3d 1366, 59 U.S.P.Q.2d 1597 (Fed. Cir. 2001).

Applicants submit that there is little disagreement as to many (but not all) of the facts underlying the Examiner’s and Applicants’ analyses of the recapture rejection. Rather, the analyses differ regarding the legal significance of those facts, in particular regarding the significance differences between the appealed claims and the claims presented, prosecuted, and issued in the ‘626 Patent.

- A. **The Answer confirms there are “significant differences” between the issued claims of the ‘626 Patent and the initial reissue claims, but errs by considering that those differences are no longer found in the present reissue claims.**

As detailed in the Brief, there are significant differences between the initial reissue claims and the issued claims of the ‘626 Patent. Among these differences is the fact that a key claim element – the requirement that the compressed ultrahigh molecular weight polyethylene (UHMWPE) is in a deformed state while cooling – is missing from the appealed claims as currently presented and as originally filed in the present application. These differences warrant a conclusion that the appealed reissue claims are drawn to an invention distinct from those of the ‘626 Patent. Thus, the broadening aspects in the appealed claims are not related to subject matter originally surrendered during prosecution of the ‘626 Patent, avoiding recapture under the second prong of *Pannu*.

The Examiner summarizes Appellants’ argument:

The Appellant agrees that the instant claims present elements broader than elements present in the claims of the ‘626 patent, i.e., patent claims 3-6, but argues that the claim recitations do not represent impermissible recapture of subject matter because the instant claims are directed to a distinct invention comprising a significant broadening never presented during prosecution of U.S. ‘626. This argument is not persuasive because the instant claims under appeal are different in scope from the claims presented in the initial application 10/141374 and restricted from the original patented claims 1-11 of U.S. ‘626. Thus *the significant differences between the issued claims of patent ‘626 and the initial reissue claims are not found in the present reissue claims.*

Answer, at page 10 (emphasis added). The highlighted sentence is factually incorrect. The “significant differences” are indeed found in the present reissue claims.

The differences among various sets of claims are shown in the following table. The aspects of the claims drawn to cooling with or without deformation are underlined.

1. Issued claim of US 6,168,626:	2. Initial reissue claim Group III:	3. Current reissue claim:
<p>3. A method for producing an ultra high molecular weight polyethylene molded block having orientation of crystal planes in a direction parallel to a compression plane, comprising</p> <p>slightly crosslinking an ultra high molecular weight polyethylene molded block having a molecular weight not less than 5 million by irradiating the block with a high energy ray and thereby introducing a very small amount of crosslinking points into molecular chains of the block, then</p> <p>heating the crosslinked ultra high molecular weight polyethylene molded block up to a compression deformable temperature,</p> <p>compression-deforming the block by compressing the block in a direction perpendicular to the compression plane so as to deform the block, and then</p> <p><u>cooling the block while keeping the block in a deformed state under pressure</u>, said block after cooling having a thickness range of 5 to 10 mm in a direction perpendicular to the compression plane.</p>	<p>40. A method for producing an ultra high molecular weight polyethylene block, comprising:</p> <p>(a) crosslinking an ultra high molecular weight polyethylene block having a molecular weight not less than 5 million by irradiating the block with a high energy radiation at a level of at least about 1 MR;</p> <p>(b) heating said crosslinked block up to a compression deformable temperature;</p> <p>(c) subjecting said heated block to pressure; and</p> <p>(d) <u>cooling said block.</u></p>	<p>40. A method for producing an ultra high molecular weight polyethylene block, comprising:</p> <p>(a) crosslinking an ultra high molecular weight polyethylene block having a molecular weight not less than 5 million by irradiating the block with a high energy radiation at a level of at least about 1 MR;</p> <p>(b) heating said crosslinked block up to a compression deformable temperature <u>below the melting point of the UHMWPE</u>;</p> <p>(c) subjecting said heated block to pressure; and</p> <p>(d) <u>cooling said block.</u></p>

Column 3 of the table shows that the current reissue claims, both as filed and as now presented, lack the “cooling without deformed state” recitation. That is, the “significant differences” between the issued claims and the initial reissue claims are still found in the current claims.

The Examiner has acknowledged that the differences between the claims of the '626 Patent and the original reissue claims (compare column 1 to column 2) were "significant," leading the claims of the reissue application to be considered to be a patentably distinct invention. Those differences remain in the current reissue claims on appeal (compare column 2 to column 3). As a result, any broadening aspects in the appealed reissue claims do not relate to surrendered subject matter, as they are directed to a different, previously unclaimed, invention.

2. **The Answer states that the current reissue claims are "significantly more narrow" in the aspect of reciting the compression deformable temperature below the melting point; but does not give this fact appropriate weight when applying the *Pannu* third prong analysis, which requires consideration of whether broadened claims are "materially narrowed."**

The recapture rule is grounded in principles of equity, as is the law of reissues in general. See, *Ball Corp. v. United States*, 729 F.2d 1429, 1435, 221 U.S.P.Q. 289, 296 (Fed. Cir. 1984), *In re Clement*, 131 F.3d 1464, 45 U.S.P.Q.2d 1161, 1165 (Fed. Cir. 1997). A finding of recapture is thus factually dependent and, Applicants submit, not susceptible to "bright line" rules which either allow or preclude broadening of reissue claims relative to claims prosecuted in the patent to be reissued. Applicants respectfully submit that the analysis underlying the present recapture rejection has been focused predominantly on selected aspects of the appealed claims that are broader than allegedly corresponding aspects of the claims of the '626 Patent, with little consideration of the countervailing narrowing imparted by the below the melting point temperature limitation of the claims. As is clear from the law, the recapture analysis cannot end with a simple conclusion that a reissue claim presents broadened aspects. Material narrowing of reissue claims can obviate such a rejection. The Answer now attempts to address the below the melting temperature limitation of the appealed claims. But, Applicants respectfully submit, the analysis is conclusory and inconsistent with both the technical significance of the below the melting point limitation and the admitted relevance of the limitation to distinguishing the art.

As discussed in the Brief, the appealed claims are significantly narrowed from those prosecuted and issued in the '626 Patent, because of their requirement that the compression deformable temperature is less than the melting point. Claim 3 (the broadest method claim) of the '626 Patent, in contrast, only requires heating to a “compression deformable temperature.” Dependent Claim 5 of the '626 Patent recites a compression deformable temperature ranging from 50 °C below the melting point to 80 °C above the melting point. Even when viewed simply from a quantitative perspective, the appealed claims subsume only about 38% of the temperature range of Claim 5 of the '626 Patent. Relative to the much broader range of temperatures subsumed by Claim 3, the appealed claims are even more significantly narrowed. Further, from a qualitative perspective, it is manifest that a process which requires deformation of a material is highly temperature dependent – heating the material above its melting point is, indeed, materially different than melting below its melting point.

After summarizing Applicants' argument at page 10 and 11 of the Answer, the Examiner states:

While the focus on compression of crosslinked UHMWPE at a temperature below the melting point required in the instant claims is significantly more narrow than the recitation of temperatures ranging from below to above the melting point of the crosslinked UHMWPE in the issued patent claims, the narrow focus is not considered to be sufficient to allow for broadening of other significant aspects of the patented method claims. *Emphasis added.*

The Examiner thus recognizes the significance of the added limitation of the appealed claims. Nevertheless, the Examiner denies that the “significantly more narrow” claim is materially narrowed so as to avoid recapture pursuant to the third prong of the *Pannu* analysis. Under this analysis, the limitation can be somehow “significantly more narrow,” but not “materially narrowed” to avoid recapture.

The finding that a claim limitation makes an aspect (or “focus,” as stated in the Answer) “significantly more narrow” is highly probative of the factual inquiry whether the claim is “materially narrowed” to avoid the recapture rule. If the narrowing is significant, it should be material, and *vice versa*.

Rather, the Examiner’s analysis appears to wholly deny the relevance of a narrowing limitation as a matter of law. The Examiner states, “The limitation with respect to subjecting crosslinked UHMWPE to pressure at a temperature below the melting point required in the instant claims is considered to be significant narrowing *only if the additional limitations of the patented claims are retained rather than broadened.*” Answer, at page 11 (emphasis added). As so stated, any claim which broadens (i.e., does not retain) a claim element violates the recapture rule, regardless of the existence of narrowing aspects. This, of course, is not the law of recapture. Such a legal formulation is directly contrary to *Pannu* and *In re Clement*.

As discussed in the Brief, the material significance of the below the melting point limitation in the appealed claims is evidenced by the fact that the limitation is not completely unrelated to a rejection made during prosecution of the original patent. See, *In re Clement*, 45 U.S.P.Q.2d 1161 (Fed. Circ. 1997). In an attempt to refute this point, however, the Examiner states,

While the limitation would have distinguished over some of the prior art references it is not related to any grounds of rejection made during the prosecution. This argument is unpersuasive because the instant narrower limitation “temperature below the melting point of the UHMWPE” was present in the broader limitation “temperature is in a range of 50 °C lower than a melting temperature of the crosslinked ultra high molecular weight polyethylene to 80 °C higher than the melting temperature” in claim 5 prosecuted in US ‘626.

Answer, at page 12 - 13. Later, the Examiner states,

Claim 5 of the issued Patent 6,168,626 recites “the compression-deformable temperature is in a range of 50 °C lower than a melting temperature of the crosslinked ultra high molecular weight polyethylene to 80 °C higher than

the melting temperature.” Therefor the issues of heating to a temperature lower than the melting point was considered in the prosecution of US 6,168,626. The narrowing of the compression deformable temperature recitation *is not considered to be directed to an amendment and/or argument made to overcome a prior art rejection in the original prosecution* and thus there is recapture of surrendered material.

Answer, at page 14 (emphasis added).

Applicants submit that the Examiner’s analysis misapprehends *In re Clement*, and imposes requirements not supported by the case law regarding the timing of when the limitation must have been presented, the scope of the analysis relative to the rejection, or both.

First of all, the Examiner’s analysis appears to require that the below the melting temperature limitation must be directed to an amendment or argument that was actually presented during original prosecution. *In re Clement* makes no such requirement. (Indeed, if the limitation had been actually presented, it could not be a new limitation added during reissue.) Rather, *In re Clement* analysis is retrospective. It only requires that the limitation be germane to a rejection, i.e., it would have had significance in the analysis of a rejection made during original prosecution if it had been presented.

The fact that the below the melting point limitation is subsumed within a broader temperature range in prosecuted claims is likewise irrelevant. Indeed, it is the narrowing of the broader range to subsume *only* heating below the melting point that has operated to distinguish the art, as recognized by the Examiner. This limitation – which now excludes heating at or above the melting point – was not considered during original prosecution of the ‘626 Patent. Indeed, the Examiner’s statement that this limitation “was considered” is at odds with the later statement that the limitation was not “directed to an amendment and/or argument made to overcome a prior art rejection in the original prosecution”

Further, the apparent focus of the Examiner's analysis on the specific limitation itself is neither supported by *In re Clement*, nor consistent with the "invention as a whole" standard for claim analysis. The analysis in *In re Clement* states,

"If the reissue claims is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim...."

Id., at 1165 (emphasis added). As so articulated by the Court, the relevance of the subject claim aspect is to the "prior art rejection," without regard to whether the specific aspect itself was directed to an argument or amendment made during original prosecution. It is axiomatic that it is the entirety of a claimed invention which is the subject of any given rejection – not simply an individual claim element. Insofar as the below the melting point claim element is effective to distinguish the art cited in prosecution of the '626 Patent, it is manifestly relevant to the rejection, as it is part of the invention as a whole. Applicants submit that one cannot parse out individual elements as being directed to an argument or amendment made during original prosecution. Such is certainly not the rule articulated in *In re Clement*.

Following the Examiner's analysis, the fact that the below the melting point limitation is "not directed to an amendment and/or argument made to overcome a prior art rejection in the original prosecution" underscores the materiality of the below the melting point limitation consistent with *Hester Industries v. Stein, Inc.*, 46 U.S.P.Q.2d 1641 (Fed. Cir. 1998). The Court in *Hester Industries* stated,

Finally, because the recapture rule may be avoided in some circumstances, we consider whether the reissue claims were materially narrowed in other respects. See, e.g. , *Mentor* , 998 F.2d at 996, 27 USPQ2d at 1525 ("Reissue claims that are broader in certain respects and narrower in others may avoid the effect of the recapture rule."); *Clement* , 131 F.3d at 1470, 45 USPQ2d at 1165. For example, in *Ball* the recapture rule was avoided because the reissue claims were sufficiently narrowed (described by the court as

“fundamental narrowness”) despite the broadened aspects of the claims. 729 F.2d at 1438, 221 USPQ at 296. In the context of a surrender by way of argument, this principle, in appropriate cases, may operate to overcome the recapture rule when the reissue claims are materially narrower in other overlooked aspects of the invention. The purpose of this exception to the recapture rule is to allow the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects.

Id., 1649, 1650 (emphasis added). Applicants submit that the below the melting point limitation is just such an “overlooked aspect” of the invention. Indeed, as now argued by the Examiner, this limitation was directed to an amendment or argument presented during prosecution of the ‘626 Patent. That is, the limitation added to the appealed reissue claims was overlooked during prosecution of the ‘626 Patent.

The *Hester Industries* court provided no explicit guidance on what is meant by “overlooked.” The M.P.E.P. states, “A limitation that had been prosecuted in the original patent application is not directed to “overlooked aspects”” §1412.02(V), Manual of Patent Examining Procedure (8th ed 2001) (Rev 7, July 2008). Such is not the case with respect to the below the melting point limitation; the limitation was never presented (as recognized by the Examiner). Moreover, the present case can be distinguished from the facts of *Hester Industries*, where recapture was found because an added limitation was not “overlooked.” Specifically, the limitations added during prosecution of the reissue claims in *Hester Industries* were found to have been included in the claims as filed, and to have been argued to overcome a rejection. Such is not the case with respect to the below the melting point limitation of the appealed claims.

In sum, Applicants’ reissue claims, while having elements arguably broader than corresponding elements in the ‘626 Patent claims, embody a broadening element (the absence of the cooling in a deformed state) which is patentably significant, such that the appealed claims define a patentably distinct invention. That fact, in and of itself, renders moot the recapture rejection.

Furthermore, the claims are also materially narrowed in a way to obviate the recapture rejection, by inclusion of the below the melting point heating limitation. This materiality is evidenced not just technically, but by the relevance of the limitation to the prosecution of the '626 Patent (as per *In re Clements*) and as an overlooked aspect of the invention (as per *Hester Industries*). Thus, the reissue claims do not violate the recapture rule. Applicants respectfully request the rejection be reversed.

II. The claims are non-obvious in view of the combined *Zachariades* and *Kitamaru* references because the combination is made only through impermissible hindsight, as is evident from the Answer.

Claims 40, 41, 43, 45-53, 84, 85, 87, 89-97 and 100-101 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,030,402, *Zachariades*, issued July 9, 1991 (hereinafter "*Zachariades* '402" in view of U.S. Patent No. 3,886,056, *Kitamaru*, issued May 27, 1975 (hereinafter "*Kitamaru*").

As discussed in the Brief, the present obviousness rejection attempts to reach the subject matter of the claims by (1) combining two references dealing with fundamentally different material technologies, (2) combining them in a fashion inconsistent with the process taught by the primary *Zachariades* '402 reference, and (3) arbitrarily selecting only certain features of the secondary *Kitamaru* reference for the combination. This combination represents an improper reconstruction of the references, guided only by impermissible hindsight use of Applicants' disclosure.

In particular, *Zachariades* '402 teaches heating thick polyethylene articles (such as prosthetic components) at a temperature below the melting point in order to compression deform, but does not teach irradiating before heating. *Kitamaru*, on the other hand, describes production of polyethylene fibers, films and sheets by extension above the melting point after irradiation. To reach the claims, one of the features of *Kitamaru* (irradiation before heating) must be combined with *Zachariades* '402, but another aspect (melting the polyethylene) must not be combined with

Zachariades '402. Applicants submit this combination is only made with the benefit of hindsight reconstruction, notwithstanding the fact that the references deal with different material properties and the combination is inconsistent with the teachings of *Zachariades* '402.

Addressing Applicants' argument, the Answer (page 16) states (emphasis added):

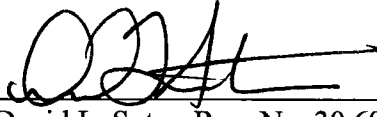
Appellant argues that no rational[e] is provided for selecting the irradiation step taught by Kitamaru et al. and not the application of pressure at a temperature above the melting point. *Zachariades* is relied upon for heating at a temperature below the melting point in order to compression deform polyethylene in the solid state. Modification of this process step taught by *Zachariades* is not required to arrive at the instantly claimed method.

This analysis underscores the fact that disparate teachings of the prior art were, in fact, pieced together using the claims as a guide or roadmap. It also overlooks the fact that one of ordinary skill would not combine references dealing with different material technologies or combine them in a fashion inconsistent with their teachings. Thus, it appears the only reason the *Kitamaru* feature of deforming above the melting point was not combined with *Zachariades* '402 was that such a combination would not have led to the subject matter of the rejected claims. Such an analysis is impermissible. See, *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2d 1385, 1397 (2007). ("A fact finder should be aware ... of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning") (internal citations omitted). *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 U.S.P.Q.2d 1321, 1329 (Fed. Cir. 1998) ("Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention."). See also *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."). A motivation to combine is still required, but "the motivation to combine references can not come from the invention itself." *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products*,

Inc., 21 F.3d 1068, 1072, 30 U.S.P.Q.2d 1377, 1380 (Fed. Cir. 1993). At least because of this (as well as the other reasons discussed in the Brief), a proper *prima facie* case of obviousness is not supported, and the rejections under 35 USC § 103(a) should be reversed.

Respectfully submitted,

Dated: March 1, 2010

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